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PATENT

#19  
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Feb. 9, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Shirley *et al.*

Appl. No.: 09/285,429

Group Art Unit: 1653

Filed: April 2, 1999

Examiner: F. Moezie

For: INJECTABLE FORMULATIONS CONTAINING SUCCINATE

December 19, 2001

Commissioner for Patents  
Washington, DC 20231

AMENDMENT AND RESPONSE  
UNDER 37 C.F.R. §1.111

Sir:

Responsive to the Office Action mailed September 21, 2001, reexamination and reconsideration of the above-identified application is respectfully requested in view of the following remarks.

REMARKS

Status of the Claims

Claims 1-14 and 21-36 are now pending. The Examiner's comments are addressed below in the order set forth in the Office Action.

Summary of the Invention

Applicants have discovered that pharmaceutical formulations that are buffered with succinate at a concentration of about 10 mM to about 40 mM result in reduced pain on injection relative to those formulated with other buffers at similar concentrations. For instance, using a nociceptor activation model designed to predict the pain of injection produced by formulations, Applicants have demonstrated that injection of a 10 mM succinate formulation is no more painful than injection of normal saline. See Example 4 and Figure 7. Additional data from a study in New Zealand white rabbits indicates that injection of IGF buffered with 10 mM